NCIC HPV
Sent by: Mary-Beth

05/27/2003 02:48 PM

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CC:

Subject: Environmental Defense comments on Methyl 3.3-dimethyl-4. pentenoate (CAS# 63721-05-1)



Richard_Denison@environmentaldefense.org on 05/27/2003 11:38:07 AM

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Subject: Environmental Defense comments on Methyl 3,3-dimethyl-4, pentenoate (CAS# 63721-05-1)

(Submitted via Internet 5/27/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and NATALIE RUTHERFORD@fmc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Methyl 3,3-dimethyl-4, pentenoate (CAS# 63721-05-1).

This test plan and robust summary for methyl 3,3-dimethyl-4, pentenoate, also referred to as DVester Step 1, was prepared by FMC Corporation. The test plan is one page long and not very informative, indicating via a checklist only whether or not there are available data for a particular HPV endpoint and whether additional testing is required.

The sponsor claims that no DVester Step 1 is present in any consumer products, but does not share any information as to which consumer products the chemical is used to synthesize. Therefore, we cannot evaluate the potential for human exposure. The sponsor also claims that DVester Step 1 is used entirely as a closed-system intermediate. However, the robust summary indicates that wastewater monitoring samples contain an average of $1.55\ \text{ppm}$ and in-house monitoring data revealed that some facilities had approximately 1 ppm in the air. Obviously, based on these results, DVester Step 1 is not entirely a closed-system intermediate and the potential exists for chronic human exposure. The sponsor also states that DVester is not currently transported, but that it has been as recently as 2002, so we must assume that this material will be transported at some time in the future.

The sponsor appears to have conducted a reasonable evaluation of existing data and has appropriately noted the cases where data are lacking or unacceptable for some reason. We agree with all of the proposals for further testing, but disagree with the sponsor's claim that a repeat dose study is not needed; we recommend that the sponsor conduct a combined repeat dose/reproductive/ developmental toxicity screen instead of only a developmental toxicity screen. Specific comments are as follows:

- 1. We agree with the sponsor's proposal to conduct studies on physical/chemical properties, biodegradation, acute toxicity in aquatic invertebrates, and toxicity in aquatic plants, as this information is either not available (biodegradation and ecological toxicity) or unreliable (physicochemical properties).
- 2. Acute toxicity studies in rats demonstrate that DVester Step 1 has little acute toxicity.

- 3. In vitro genetic toxicity, as assessed by data from Ames tests, suggest that DVester Stepl does not appear to be a mutagen. However, no in vivo studies are available so we concur with the sponsor's proposal to conduct such a test.
- 4. Since there is apparently some release of DVester environment and no repeat dose data are available, we disagree with the sponsor's claim that repeat dose studies are not needed. In order to minimize the use of animals, we recommend that a combined reproductive/developmental/repeat dose toxicity study be conducted on DVester Step 1.

Thank you for this opportunity to comment.

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